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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/109,119 06/30/98 BOLDT B GTIBEN.001

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HM12/0827

EXAMINER

PAWUL, A

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 08/27/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/109,119

Applicant(s)

Boldt, Etal

Examiner  
Anna Pawul

Group Art Unit  
1653



☐ Responsive to communication(s) filed on \_\_\_\_\_.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-20 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-20 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 8, 13, 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. The term "substantially complementary" in claims 1, 13, and 17 is a relative term which renders the claim indefinite. The term "substantially complementary" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.
4. The term "diagnostic section" in claims 1, 13, and 17 is a relative term which renders the claim indefinite. The term "diagnostic section" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Using this term renders the target of the primer indefinite.
5. The term "quantifying presence of the complex" in claim 16 is a relative term which renders the claim indefinite. The term "quantifying presence of the complex" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and

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one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

There is nothing in the specification that indicates what a "quantifying presence" is.

6. Claim 8 refers to a "step g" in the method of claim 7. This is vague and indefinite, it is not clear which method and step this claim is referring to. Please clarify.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

8. Claims 1-20 rejected under 35 U.S.C. 102(e) as being anticipated by Harris et al, U.S. Patent # 5849544.

Harris teaches a method by which a specific DNA which may have clinical significance is amplified and captured to a solid support and the said DNA is later detected (abstract, claim 15, column 1, lines 40-56 and column 24, lines 4-24). This method includes capturing the

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amplified polynucleotide strands to a probe and denaturing them (column 1, lines 40-56, column 3 & 4). The amplified polynucleotides are separated into single-stranded polynucleotides (column 4, lines 25-27).

Harris also teaches the support can be a microtiter plate (column 6, lines 22-33). They also teach to using enzyme labels, florescent labels, biotin and streptavin as reporter labels (claim 14, column 5, line 37). Harris teaches that this process can be used to detect a point mutation (claim 15, column 24, line 16) which is interpreted to be the same as a mismatch.

In addition Harris teaches the use of a kit for testing the DNA for inherited or not inherited conditions (column 1, lines 58-67, column 2, lines 7-17, column 24, lines 4-50).

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Pawul whose telephone number is (703) 305-0806. The examiner can normally be reached Monday-Friday 7:30 AM to 4:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bradley Sisson, can be normally reached on Monday-Thursday from 8:00 AM to 5:00 PM (EST) and whose telephone number is (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196. Papers related to

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this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to group 180 via the PTO Fax Center located in Crystal Mall 1. Papers may be submitted Monday-Friday between 8:00 AM and 4:00 PM (EST). The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 fax Center number is (703) 305-3014 or (703) 308-4242.

AP 8-20-99

A handwritten signature in cursive script that reads "Eggerton Campbell".

EGGERTON A. CAMPBELL  
PRIMARY EXAMINER